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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,713	04/04/2001	Matthew During	DUR01-NP001	3131
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THOMAS JEFFERSON UNIVERSITY
INTELLECTUAL PROPERTY DIVISION
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EXAMINER
KATCHEVES, KONSTANTINA T

ART UNIT	PAPER NUMBER
1636	7

DATE MAILED: 05/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/825,713

Applicant(s)

DURING ET AL.

Examiner

Konstantina Katcheves

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 28 February 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11. 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-18 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____

- 4) Interview Summary (PTO-413) Paper No(s) _____
 5) Notice of Informal Patent Application (PTO-152)
 6) Other: _____

DETAILED ACTION

Claims 1-19 are pending in the present application.

Response to Amendment

The rejection of claims 1-4, 6, 7, 9, 10-15 and 17-19 under 35 U.S.C. 103(a) as being unpatentable over by Ourednik et al. and Kopen et al. has been withdrawn in response to Applicant's Amendment filed 28 February 2002.

The rejection of claims 1-7, 9, 10-15 and 17-19 under 35 U.S.C. 103(a) as being unpatentable over Ourednik in view of Kopen and further in view of Eglitis et al. has been withdrawn in response to Applicant's Amendment filed 28 February 2002.

The rejection of claims 1-4 and 7-19 under 35 U.S.C. 103(a) as being unpatentable over Ourednik in view of Kopen and further in view of Cheng et al. has been withdrawn in response to Applicant's Amendment filed 28 February 2002.

The rejection of claims 1-19 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been withdrawn in response to Applicant's Amendment filed 28 February 2002.

Claims 1-19 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods drawn to mouse and rat models, does not reasonably provide enablement for methods drawn to the treatment of human subjects for the reasons of record set forth in the Office Action mailed 29 August 2001.

Response to Arguments

Claims 1-19 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods drawn to mouse and rat models, does not reasonably provide enablement for methods drawn to the treatment of human subjects for the reasons of record set forth in the Office Action mailed 29 August 2001. Applicant's arguments filed 28 February 2002 have been fully considered but they are not persuasive.

Applicant recites MPEP §2107.02 and §2164.03 stating that results from human clinical trials are not required and that animal models in the specification constitute a working example if the example is known to correlate with the invention. Although Applicant's invention provides examples with a rat and mouse model, this does not necessarily enable Applicant for the full scope of the claimed invention. As referenced in the prior Office Action, Martinez teaches that research on neural stem cells and progenitors in the central nervous system is "still in its infancy" requiring more research and knowledge of the mechanisms regulating stem cell and neural progenitor differentiation. Applicant asserts that Martinez is inappropriate for establishing the state of and the predictability of the art because the reference was published in 1997 whereas the present Application was filed on 4 April 2001. Applicant has stated that the art has progressed since 1997, however, has failed to provide any evidence supporting this general assertion.

Moreover, the state of the art remains unpredictable such that one of skill in the art would not find that Applicant is enabled for anything more than the mouse and rat models recited in the claims. A press release from the National Institute of Neurological Disorders and Stroke on 09 January 2002 recognizes the continuing need for research in the area of stem cell

transplantation. See www.ninds.nih.gov/news_and_events. The press release reviews research by Bjorklund et al. (*PNAS* Björklund et al. Vol. 99 No.4 2002) and states:

While the results of this study are intriguing, they also reveal the need for additional research. The transplanted cells did not survive in 6 of the 25 rats treated, and 5 of the animals developed tumors near the site of the transplants within the first 9 weeks. These complications illustrate the importance of learning how to control the differentiation and proliferation of stem cells before planning similar therapies in humans. See e.g. page 2349, first sentence, second column.

It is clear from the Bjorklund et al. reference and the accompanying press release by the National Institute of Neurological Disorders and Stroke that research is still required to translate data and results from rat and mouse models to human efficacy and success.

Applicant further argues that stem cells of myeloid origin are effective gene delivery vehicles. Applicant cites *In re Cortright*, 49 USPQ2d 1464, 1469 Fed Cir 1999) for the proposition that "it is not a requirement of patentability that an inventor correctly set forth, or even know, how or why the invention works." It is, however, a requirement of patentability that Applicant provide of skill in the art with an adequate disclosure such that one of skill in the art is capable of making and using the present invention without undue experimentation. This standard is well-settled in the law as set forth in *In re Wands*, 8 USPQ2d 1400, 1404 (CAFC 1988) citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986). Applicant has not taught in the specification how one of skill in the art may overcome the unpredictability and lack of sophistication in stem cell therapy and gene therapy such that one of skill in the art may practice the invention in all mammals, including humans. Applicant has merely provided examples in Parkinsonian rats and mice without data or evidence supporting a correlation between these

models and other mammals, including humans. Therefore, Applicant has failed to fully enable the scope of the claimed invention.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (703) 305-1999. The examiner can normally be reached on Monday through Friday 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers

for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3388.

Konstantina Katcheves
May 17, 2002

Remyyucel
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SUPERVISORY PATENT EXAMINER
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